(19)

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
23 August 2007 (23.08.2007)

PCT

(10) International Publication Number
WO 2007/094002 A2

(51) International Patent Classification:
*A61B 19/00* (2006.01)

(21) International Application Number:
PCT/IL2007/000215

(22) International Filing Date:
15 February 2007 (15.02.2007)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/773,931 16 February 2006 (16.02.2006) US
PCT/IB2006/052770
10 August 2006 (10.08.2006) IB

(71) Applicant (*for all designated States except US*): **NAVOTEK MEDICAL LTD.** [IL/IL]; 5 HaCarmel Street, P.o. Box 201, 20692 Yokneam (IL).

(72) Inventors; and
(75) Inventors/Applicants (*for US only*): **NEUSTADTER, David, Maier** [IL/IL]; 3/3 Ruth Hamoavia Street, 42756 Natania (IL). **KORNBLAU, Giora** [IL/IL]; 27 Hagadish Street, 30500 Binyamina (IL).

(74) Agents: **G.E. EHRLICH (1995) LTD.** et al.; 11 Menachem Begin Street, 52521 Ramat Gan (IL).

(81) Designated States (*unless otherwise indicated, for every kind of national protection available*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

**Published:**
— *without international search report and to be republished upon receipt of that report*

*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

(54) **Title:** LOCATION INDICATION BY POINTING TO AN INTRABODY RADIATION SOURCE

(57) **Abstract:** The application relates to a method of providing a visual indication to a position of an object inside a subject's body and/or to a variable that may be determined according to said position, the method comprising: (a) detecting radiation emitted by a radiation source inside the subject's body; (b) analyzing the radiation to determine the position of the object; and (c) projecting on at least a portion of the subject's body an image providing a visual indication of the determined position and/or of said variable.

WO 2007/094002 A2

# LOCATION INDICATION BY POINTING TO AN INTRABODY RADIATION SOURCE

## RELATED APPLICATION DATA:

The present application is a continuation in part of PCT/IL2005/000871 filed on August 11, 2005, and is also a continuation in part of PCT/IL2005/001101 filed on October 19, 2005 the disclosures of which are fully incorporated herein by reference.

In addition, the present application claims the benefit under 35 USC 119(e) of U.S. Provisional Application Nos. 60/600,725 filed on August 12, 2004; entitled "Medical Navigation System Based on Differential Sensor"; 60/619,792 filed on October 19, 2004, entitled "Using a Catheter Or Guidewire Tracking System to Provide Positional Feedback for an Automated Catheter or Guidewire Navigation System", 60/619,897 filed on October 19, 2004, entitled "Using a Radioactive Source as the Tracked Element of a Tracking System", and 60/619,898 19 October, 2004, entitled "Tracking a Catheter Tip by Measuring its Distance From a Tracked Guide Wire Tip" the disclosures of which are incorporated herein by reference.

This application is related to a co-pending application identified as attorney docket 503/05045 entitled "Localization of a Radioactive Source" filed the same day as this application.

## FIELD OF THE INVENTION

The present invention relates to indicating a location of an intrabody object.

## BACKGROUND OF THE INVENTION

Techniques for indicating the position of an intrabody object are known in the art. Usually, position of intrabody object is indicated on an image display. For example US 2005/0085717 to Shahidi et al. describes a display with 3D-images of an internal body and markings on the images to indicate the position of a surgical device in the body.

JP 01-288250 describes an X-ray CT imaging system used to identify the position of a tumor inside a body and indicates the position by pointing two laser beams to the position of the tumor.

WO 2004/000151 to Dalton describes a display device oriented with respect to a partially reflective device such that the display image appears superimposed to a viewer over the object.

Co-pending PCT application WO 2006/016368 by the inventors of the present invention teaches the use of directional sensors for real time measuring of the 3 dimensional position of a gamma emitting source. The disclosures of this patent application is fully incorporated herein by reference.

US 6,603,124 to Maublant teaches the use of a laser pointer mounted on a directional sensor, wherein the sensor detects a direction towards a gamma emitting source and aims the laser points at it.

## SUMMARY OF THE INVENTION

An aspect of some embodiments of the invention relates to projecting on a subject's body an image indicative of the position of a radiation source inside the subject's body. In exemplary embodiments of the invention, the image is projected using an LCD projector, a DLP (digital light processing) projector or any other type of image or light projector. Optionally, the image comprises a spot of light indicative of the position of the radiation source. Optionally, the spot of light is surrounded with a dark background. Optionally, the image also contains visual indications of internal organs of the patient, for instance the ribs of a patient. Optionally, a data base of images of the patient is obtained from an imaging system, for instance, X-ray, CT, MRI, etc. and the position of the radiation source is indicated on images selected from this data base. The image from the database together and an indication of the position of the radiation source are projected on the patient. Optionally, the projected image contains or includes a graphic display of a parameter of interest to the user, such as the position in the respiratory cycle, (end of inspiration, beginning of inspiration, etc), patient's ECG, and others.

In an embodiment of the invention, the projector is stationary, and movement of the radiation source is indicated by changing the image, for instance, changing the place of the light spot in the image.

In an exemplary embodiment of the invention, the image is dynamic, for example, being updated from time to time, for instance, every 5 seconds, every second, 5 times per second, 20 times per second, or at any larger, smaller, or intermediate rate.

In an embodiment of the invention, the image is updated in synchronization with in a manner allowing visual indication of the patient's breathing cycle and the current position of the patient in this cycle. Optionally, this is done with the aid a

breathing sensor, alternatively or additionally, following the patient's breathing cycle may be aided with detection and analysis of movements related to breathing, for instance by analyzing changes in sensor position.

In an exemplary embodiment of the invention, the image indicates, for example, by a moving indicator, a previous and/or a future path of the source. Future path may be predicted based on detected past path and an extrapolation model.

In an exemplary embodiment of the invention, the radiation source is the source described in US patent application No. 60/773,931, incorporated herein by reference.

In an exemplary embodiment of the invention the position sensor is the sensor described in WO 2006/016368, the disclosure of which is fully incorporated herein by reference.

Optionally, the radiation source comprises a tissue that absorbed a radiopharmaceutical.

In an exemplary embodiment of the invention, two or more markers are tracked and indicated simultaneously. Optionally, two or more of the markers are tracked using mutually different tracking methods, for example, one marker is tracked with methods based on magnetic fields and another based on radiation detection; one based on detection of radioactive radiation, and another tracked with CT, etc.

Optionally, the radiation source is visible and distinguishable also by means other than detection of the radiation of the source. For instance, the radiation source may include a radio-opaque portion. In an exemplary embodiment of the invention, the radio-opaque portion allows visualization of the radiation source using X-ray based imaging methods. In such a case, the position of the source may be found by the radiation detection, and by X-ray, and the results obtained this way may be used for calibrating the two radiation detection system in respect of the X-ray system. Alternatively or additionally, the radiation source is visible and distinguishable on MR and/or ultrasound images.

An aspect of some embodiments of the present invention relates to a position determination system configured to determine a position of a radiation source of the type described above with sufficient accuracy to accurately indicate the position of the source on an image that is projected on the body and registered with it. In an

exemplary embodiment of the invention, the position of the source is tracked using one or more, optionally two or more, directionally-sensitive detectors.

In an exemplary embodiment of the invention, the accuracy of the position indication is limited by the accuracy of the detection of the radiation source, since registration between the radiation detector and the projector or image producer is much better, as it may be measured off line. Since the position of a radioactive source is measurable with an accuracy better than 5, 2, or 1 mm, this is also the accuracy of the position indication according to some embodiments of the invention. In an exemplary embodiment of the invention, the position indicated on the image is accurate enough to provide clinically useful guidance for a medical procedure, such as, but not limited to, biopsy, minimally invasive surgery, external beam therapy, rf-ablation, cryo-ablation, surgical guidance, and electrode placement.

In an exemplary embodiment of the invention, aiming includes changing the projected image. Optionally, changing comprises replacing.

In an exemplary embodiment of the invention, the system relies upon one or more directional sensors to determine the position of the position indicator. The directional sensors optionally include collimators, which are optionally slat collimators. Optionally the light is projected at the determined position or at a target with a defined spatial relationship with respect to the determined position.

In some exemplary embodiments of the invention, the system automatically provides the position as an output to an image-producer which produces images indicative of the sensed position of the radiation source. Optionally, the output is manually entered into the image producer after being displayed to an operator of the image producer. Optionally, the position indicator is provided on a background comprising an anatomical image.

In some exemplary embodiments of the invention, the position determination system is integrated into an image producing system which produces the images to be projected.

In some exemplary embodiments of the invention, the directional sensors and the image producer are located at different locations. For example the directional sensors are located in the patient couch and the image projector above the patient. In another exemplary embodiment, the directional sensors are located above the patient

or on one side of the patient and the image projector is located on the opposite side of the patient.

Thus, there is provided in accordance with an exemplary embodiment of the invention a method of providing a visual indication to a position of an object inside a subject's body and/or to a variable that may be determined according to said position, the method comprising:

(a) detecting radiation, optionally radioactive radiation, emitted by a radiation source inside the subject's body;

(b) analyzing the radiation to determine the position of the object; and

(c) projecting on at least a portion of the subject's body an image providing a visual indication of the determined at least one of position or variable.

In an exemplary embodiment, detecting comprises moving at least one sensor; projecting comprises operating a projector; and the position of the projector is independent of movement of the at least one sensor. Optionally, the projector is stationary.

In an exemplary embodiment, the image comprises at least one light spot surrounded with a background, and the position of the at least one light spot is indicative of the position of the object. Optionally, the background is darker than said at least one light spot.

An exemplary embodiment of the invention comprises changing the position of the visual indicator in the image. Optionally, changing comprises digitally changing the image. Optionally, changing the position of the visual indicator in the image is accompanied with changing the at least portion of the body on which the image is projected. Optionally, changing the position of the visual indicator in the image is without changing the at least portion of the body on which the image is projected.

In an exemplary embodiment of the invention, the visual indicator is indicative of at least a depth of the object inside the subject's body.

In an exemplary embodiment of the invention, the object is a tissue of said body. Alternatively, the object is a medical device.

Optionally, a method according to some embodiments of the invention comprises inserting the radiation source into the subject's body.

There is also provided in accordance with an exemplary embodiment of the invention a system for visually indicating location of an object inside a subject's body, the system comprising:

(a) at least one radiation sensor

(b) an analyzer

(c) an image producer; and

(d) an image projector,

wherein the image producer is configured to produce an image, which upon being projected on the subject's body by said projector provides visual indication of the location of the object inside the subject's body as determined by the analyzer based on analysis of radiation sensed by the at least one radiation sensor.

In an exemplary embodiment of the invention, wherein the radiation sensor is movable independently of the image projector. Optionally, the projector is stationary.

In an exemplary embodiment of the invention, the image producer produces the image based on data received from the analyzer, and the image is produced digitally.

Optionally, the system is configured for digitally changing the image or replacing the image while the projector is stationary.

In exemplary embodiment of the invention, the radiation sensor has slatted collimators.

## BRIEF DESCRIPTION OF DRAWINGS

In the figures, identical structures, elements or parts that appear in more than one figure are generally labeled with the same numeral in all the figures in which they appear. Dimensions of components and features shown in the figures are chosen for convenience and clarity of presentation and are not necessarily shown to scale. The Figures are listed below.

Fig. 1A is a schematic representation of a visual indication system according to an exemplary embodiment of the invention;

Fig. 1B is a schematic illustration of an image with visual indicators according to an embodiment of the invention;

Fig. 2 is a simplified flow diagram of an indication process according to an exemplary embodiment of the invention;

Figs. 3A and 3C are schematic representations of position indicators according to exemplary embodiments of the invention;

Figs. 3B and 3D are schematic representations of the position indicators according to exemplary embodiments of the invention depicted in Figs. 3A and 3C respectively loaded in an injection needle; and

Fig. 4 is a side view of one exemplary embodiment of directional position sensor suitable for use in some exemplary embodiments of the invention; and

## DETAILED DESCRIPTION OF EMBODIMENTS

Overview

Figs. 1A and 1B are schematic representations of exemplary visual indication systems 100 which rely upon radioactive disintegrations produced by a radiation source 400 located within a body of a patient 120. Radiation source 400 is optionally within, adjacent to or at a known geometric relationship with respect to a target 130. Optionally, target 130 is a tumor. Optionally, the tumor absorbs radioactive isotope, and functions as a radiation source. Optionally, target 130 is a medical device, for instance, a tool, an implant, a navigational instrument, a duct, etc. Optionally, target 130 is a portion of a medical device, for instance a catheter tip whose position is to be tracked in real time.

In an exemplary embodiment of the invention, source 400 broadcasts its location radially outward as radiation resulting from radioactive disintegrations. In an exemplary embodiment of the invention, the radiation includes gamma-ray photons. Optionally, a portion of this broadcast is received by one or more directional sensors 150 deployed for that purpose. Exemplary sensors 150 are described in co-pending application PCT/IL2005/000871 filed on August 11, 2005, the disclosure of which is incorporated herein by reference. A summary of that description appears herein below with reference to Fig. 4.

In an exemplary embodiment of the invention, sensors 150 employ collimators, optionally slat collimators, to determine a direction from which photons resulting from radioactive disintegrations originate. Optionally, each direction is expressed as a plane or as a linear vector. Optionally, two sensors 150 including slat collimators indicate a pair of lines which cross at a single point corresponding to a position of position indicator 400. In an exemplary embodiment of the invention, three or more sensors 150 are employed to increase the accuracy of a determined

location. Optionally, the nearest point of approach of the two, optionally three or more, lines is deemed to be the point at which the lines cross.

It should be noted that in some embodiments the positional information is 3-dimensional, while in other embodiments, it may be 2-dimensional.

Alternatively or additionally, slanted slat collimators, such as in patent application No. PCT IB2006/052770, the disclosure of which is incorporated herein by reference, are used.

Fig. 1A illustrates an exemplary semiautomatic system 100 for aiming an image (not shown) from a projector 110. In the embodiment shown, projector 110 is separate from the sensor 150, allowing aiming the projector from position and distance from patient 120 other than those of sensor(s) 150. This is advantageous, for instance, when sensors 150 are below the patient or in cases where the sensors (which must be as close as possible to the target, to improve the photon statistics) would otherwise interfere with or hinder the physician's freedom of movement.

According to the pictured exemplary system, sensors 150 optionally adjust their direction to optimize reception of the incident particles resulting from radioactive disintegrations, optionally based on a prediction of future possible positions. Once reception is optimized and/or during optimization, each sensor indicates a direction to tracking system processor 170. Processor 170 calculates a position from the direction input supplied by all of sensors 150. Optionally, processor 170 corrects for a known spatial displacement between position indicator 400 and target 130. As indicated in Fig. 1, sensors 150 may optionally be deployed above patient 120 and/or below patient 120 (e.g. built into the examination table).

Fig. 1A illustrates exemplary fully automatic embodiments in which tracking system processor 170 communicates the position output signal directly to image producer processor 180. According to this exemplary embodiment of the invention image 1000 is projected by projector 110 with visual indicator 1002 aligned with target 130 without additional operator input.

Fig. 1B illustrates an image 1000 according to an embodiment of the invention. For ease of illustration, Fig. 1B illustrates image 1000 in negative. Image 1000 comprises a black background 1002 with three bright small circles 1009. The circles compose a visual indicator 1006, shown in the Figure as an imagery circle. In operation, image 1000 is projected such that the center of indicator 1006 is indicative

of the location of radiation source 400, for instance, the center of the visual indicator is just above the radiation source. When the image is projected on the body of patient 120, circles 1009 appear as bright spots on the patient's body.

Optionally, the distance between the circles is indicative of the distance of the radiation source from the patient's surface. For instance, closer circles may indicate a more superficial radiation source, and more distant apart circles may indicate a radiation source that is deeper inside the patient body. This way, if the radiation source moves outwards or inwards, this is indicated by change in the density of the circles as they appear in the projected image.

Alternately, the color or hue of the projected spot can indicate the depth of the radiation source. Many other display techniques for adding additional information are known to those skilled in the art of image and information display.

Optionally, images are created periodically, for instance 24 times a second, each second, 25 times per minute, or any smaller, larger, or intermediate rate, so if radiation source 400 moves, the image produced has the visual indicator at another place on background 1002. As the visual indicator 1006 appears at different places on the image.

As the source moves, the detector measures a new position of the source. By updating the position of the visual indicator 1006 on the image, the image may be projected with a stationary projector 110, without compromising movement of visual indicator 1006. Nevertheless, projector 110 may be mounted on rails, for instance, to be brought to above the area in which radiation source 400 lies, or to follow the radiation source, if it moves out of the image frame.

Optionally, image 1000 comprises visual indicators indicative of not only the current position of radiation source 400. For instance, Fig. 1B also illustrates a visual indicator 1008, indicative of a path, along which source 400 moved. Optionally, path 1008 is indicated with a different color, optionally less bright than the color with which position indicator 1006 is marked. In an exemplary embodiment of the invention, a breathing sensor is provided. Many such sensors are known to those skilled in the art. Examples include impedance-based sensors, mechanical sensors, strain-gauge sensors, sensors using air bellows, optical tracking sensors, ultrasound-based sensors, etc. Alternately, the breathing is detected by analyzing repetitive movements of the source. Such methods are well known from MRI respiratory gating

where the change in MR signal is used to evaluate the position in the breathing cycle. Once the (temporal) position in the breathing cycle is known, a visual indicator of the position in the breathing cycle may be projected, optionally together with displaying an indicator indicative of the position of the radiation source. For visually indicating a position in a breathing cycle, an image associated with this portion of the breathing cycle is optionally projected on the body. Alternatively or additionally, a non-visual indicator may be displayed, for instance, a sound. Indicating the position in a breathing cycle may find use in many applications, such as biopsies, where it is important to know the position in the breathing cycle in order to insert the biopsy needle into the body at a specific point in the breathing cycle e.g. end-expiration. It would be useful to a clinician to see a display of the required position of the biopsy entry point (based on the position of the marker) projected onto the body together with receiving a visual, audio, or any other indication of the current position in the breathing cycle. In this way, the clinician would know both where to insert the needle and when to do so, without looking away from the needle.

Optionally, image 1000 comprises visual indicators indicative of not only the current position of radiation source 400. For instance, Fig. 1B also illustrates a visual indicator 1008, indicative of a path, along which source 400 has moved. Optionally, path 1008 is indicated with a different color, optionally less bright than the color with which position indicator 1006 is marked.

Fig. 2 is a simplified flow diagram of an indication method 200 according to an exemplary embodiment of the invention.

At 210 a position indicator is inserted in the body of a patient. Insertion optionally comprises implantation in, adjacent to, or at any known displacement with respect to a target tissue. In an exemplary embodiment of the invention, the target tissue is a tumor. In an exemplary embodiment of the invention, insertion comprises insertion of a medical instrument or tool with the position indicator attached to or integrated with. The position indicator optionally includes a radioactive source which is characterized by a desired activity, as described below.

At 212, a determination of the position co-ordinates of the position indicator is made based upon analysis of radiation emitted by the position indicator. Optionally, the radiation is gamma radiation resulting from radioactive disintegrations in the

position indicator. Optionally, the analysis is made by one or more position sensors, optionally directionally sensitive position sensors.

At 214, an image is created based upon the position co-ordinates determined in 212. In an exemplary embodiment of the invention, the image creation is based upon a correction which considers a known displacement between the position indicator and the target. This image creation includes registration of position co-ordinates employed by the location determination mechanism and co-ordinates employed by the image projection mechanism. Registration is discussed in greater detail herein below in the section entitled "Exemplary Registration Mechanisms."

At 216, the image produced at 214 is projected. According to exemplary embodiments of the invention, 216 may include translation of a projector along tracks and/or use of gimbals and/or robotic arms and/or application of rotational motion and/or angular adjustment.

In an exemplary embodiment of the invention, 212, 214 and 216 are repeated during the course of a single session. For example, if a catheter is inserted in the body, and there is a need to track its place within the body, 212 to 216 may be repeated every several seconds to update the image showing the location of the tip of the catheter. Optionally, in such a case the image created in 214 includes also visual indicators of the positions the catheter tip had in previous images (as shown by 1008 in Fig. 1B). Optionally, movement of the radiation source because of patient's breathing or heart beat is illustrated by the visual indicators.

Exemplary Position Indicator Configurations

Figs. 3A and 3C are schematic representations of position indicators according to exemplary embodiments of the invention. In the pictured exemplary embodiments, indicator 400 comprises a radioactive source 410 and a radio-opaque portion 420. Optionally, radio-opaque portion 420 serves as a fixation element. Optionally, additional anchoring structures 430 (Fig. 3C) are included. In an exemplary embodiment of the invention, indicator 400 is coated with a biocompatible coating. Optionally, the coating renders indicator 400 inert with respect to the body. In an exemplary embodiment of the invention, implantation of indicator 400 does not elicit an immune and/or inflammatory response.

In an exemplary embodiment depicted in Fig. 3A illustrates a spiral configuration. Optionally, the spiral configuration serves to anchor indicator 400 in

the body after it is deployed at a desired location. In an exemplary embodiment of the invention, the spiral is characterized by an elastic memory so that it tends to resume its spiral shape. In an exemplary embodiment of the figure, radio-opaque portion 420 is configured as a spiral and radioactive source 410 is concentrated at one end of indicator 400. In additional exemplary embodiments of the invention, radioactive source 410 may be concentrated in a different location with respect to the spiral or diffused along the spiral.

In an exemplary embodiment depicted in Fig. 3C illustrates a straight configuration. Optionally, a herringbone pattern of filaments 430 characterized by an elastic memory serves to anchor indicator 400 in the body after it is deployed at a desired location. In the exemplary embodiment of the figure, radio-opaque portion 420 is configured as a straight cylinder and radioactive source 410 is concentrated at one end of indicator 400. In additional exemplary embodiments of the invention, radioactive source 410 may be concentrated in a different location with respect to the cylinder or diffused along the cylinder. In an exemplary embodiment of the figure, radioactive source 410 may be a radioactive coating over a non-radioactive material.

Figs. 3B and 3D are schematic representations of the position indicators according to exemplary embodiments of the invention depicted in Figs. 3A and 3C respectively loaded in an injection needle 450. In an exemplary embodiment of the invention, needle 450 is a standard hypodermic needle, for example a 20 to 25 gauge needle.

Fig. 3B illustrates the compression of spiral portion 420 to a kinked straight configuration within needle 450.

Fig. 3D illustrates the compression of the herringbone pattern of filaments 430 within a needle 450.

Application of an ejection force (e.g. from an inserted ejection tool) from proximal side 480 causes ejection of source 400 from distal aperture 490. Elastic memory of relevant portions of source 400 causes the ejected source to tend to revert to the relevant uncompressed configuration. In an exemplary embodiment of the invention, an ejection force is supplied by an ejection tool and/or by a stream of liquid.

In an exemplary embodiment of the invention, radioactive source 410 comprises a droplet of biocompatible glue which contains a desired radioactive

isotope. Optionally, the adhesive properties of the droplet reduce a tendency to migrate or shift after injection. Optionally, the adhesive drop is contiguous and/or non-dispersing. Optionally, the droplet also includes radio-opaque material. According to this exemplary embodiment of the invention, it is source 410 itself, which adheres strongly to the surrounding tissue without benefit of a separate physical anchor (e.g. spiral 420 or filaments 430). In an exemplary embodiment of the invention, a large (2-3 mm in diameter) biocompatible glue droplet, optionally including radio-opaque material can be injected through a narrow (23-25 gauge) needle since the glue is in a liquid or gel state at the time of injection. Optionally, source 410 is biodegradable and begins to lose integrity to a significant degree after 8-12 weeks. Optionally, source 410 is metabolized and the radio-isotope contained therein is excreted from the body. Optionally, the radio-isotope particles within the glue droplet are individually coated with a biocompatible material so that they remain biocompatible as the glue degrades and the particles disperse and are excreted from the body. Optionally, the glue droplet is injected in a liquid or semi-liquid state and sets to a solid mass after injection. In an exemplary embodiment of the invention, the amount of radioactivity per unit volume is adjusted according to the specific application.

Biocompatible glues suitable for use in the context of exemplary embodiments of the invention are commercially available and one of ordinary skill in the art will be able to select a suitable glue for a contemplated exemplary embodiment. Examples of biocompatible glues include, but are not limited to, Omnex (Closure Medical Corporation, Raleigh, NC) and BioGlue (Cryolife, Atlanta, GA).

According to various exemplary embodiments of the invention, the biocompatible glue may be a two-component glue (e.g. BioGlue, Cryolife, Atlanta, GA; USA) or a one-component glue which hardens upon contact with human tissue (e.g. Omnex, Closure Medical Corporation, Raleigh, NC; USA), or a glue that is hardened by the application of a transformation energy (e.g. UV light; heat; or ultrasound).

In an exemplary embodiment of the invention, a radioactive source 410 comprising a droplet of biocompatible glue which contains a desired radioactive isotope is provided as part of a kit including an injection tool. Optionally, the injection tool mixes glue components as the glue is being injected.

In an exemplary embodiment of the invention, the injection tool is a transparent syringe marked with a scale so that the amount of glue injected is readily apparent to an operator. Optionally, the scale is marked in volume and/or drop diameter. In an exemplary embodiment of the invention, there is a knob, slider, or other mechanical actuator on the injection tool which can be positioned to a certain volume or drop diameter marking which causes the appropriate amount of glue to be injected when the injection tool is activated. In an exemplary embodiment of the invention, the injection tool includes an inflatable balloon at the end of the applicator to create a space in the tissue for the bead of glue to fill. Optionally, the injection tool applies a transformation energy.

Exemplary Registration Mechanisms

In an exemplary embodiment of the invention, sensors 150 are rigidly mounted on the patient bed and projector 110 is stationary. According to this exemplary embodiment, a one-time calibration procedure is performed during manufacturing, installation or periodically, and the tracking and image producing systems are permanently aligned, or registered, with respect to one another.

In additional exemplary embodiments of the invention, sensors 150 and projector 110 may move in respect of each other. According to these exemplary embodiments of the invention, sensors 150 are registered with projector 110 using some position and orientation determination system, known in the field *per se*. Known position and orientation determination systems include, but are not limited to, optical, ultrasound, electromagnetic and mechanical systems. A brief description of an exemplary optical tracking system useful in aligning a sensor array with a radiation therapy system can be found in "Realtime Method to Locate and Track Targets in Radiotherapy" by Kupelian and Mahadaven, Business Briefing US Oncology Review 2006, p44-46. This article is fully incorporated herein by reference. One of ordinary skill in the art will be able to select an available position and orientation determination system and incorporate it into the context of the present invention.

Construction Considerations

In an exemplary embodiment of the invention, a small radiation source 410 is coupled to a relatively large position indicator 400. Optionally, use of a small radiation source 410 (e.g. 0.5 mm to 1 mm diameter) permits sensor 150 to more accurately determine a direction from which a signal originates. Optionally, a large

radio-opaque portion 420 is easily visualized in a fluorography image. In an exemplary embodiment of the invention, radio-opaque portion 420 has a length of 1, 2, 3, or 4 cm or lesser or intermediate or greater lengths.

Position of indicator 400 with respect to target 130 may be measured by, for example X-Ray, fluoroscopy, CT, MRI or ultrasound. In an exemplary embodiment of the invention, a 3D measurement of relative position is made.

Exemplary Position Sensor

Fig. 4 is a perspective view of one exemplary embodiment of directional position sensor 150 suitable for use in some exemplary embodiments of the invention (e.g. system 100 as depicted in Fig. 1A).

Fig. 4 illustrates one exemplary embodiment of a sensor 150 configured with a plurality of radiation detectors 522 and a plurality of protruding radiation shields 536 interspersed between the plurality of radiation detectors 522. In an exemplary embodiment of the invention, each detector 522 is characterized by a width 518 of 2mm and a length 514 of 10 cm. In an exemplary embodiment of the invention, shields 536 are characterized by a height 535 of 5 cm and a width 537 at their base of 4 mm.

According to this exemplary embodiment, plurality of radiation detectors 522 is organized in pairs, each pair having a first member 521 and a second member 523. Each protruding radiation shield 536 of the plurality of protruding radiation shields is located between first member 521 and second member 523 of the pair of radiation detectors 522. According to this embodiment, sensor module 150 is capable of rotating the radiation detectors 522 through a series of rotation angles 532 about axis 516 so that receipt of radiation from a radiation source upon radiation detectors 522 varies with rotation angle 532. Each radiation detector produces an output signal.

Optionally, analytic circuitry sums output signals from all first members 521 to produce a first sum and all second members 523 to produce a second sum. Assuming that all radiation detectors 522 are identical, when the sensor is aimed directly at the center of mass of the radiation source (target rotation angle 532), the first sum and the second sum are equivalent. Use of multiple shields 536 insures that the total output for the entire module 150 increases rapidly with even a very slight change in rotation angle 532 in either direction. Alternately, or additionally, the sign

of the total output for the entire module 150 indicates the direction of rotation required to reach the desired rotation angle 532 at which total output for the entire sensor 150. Optionally, sensor 150 is characterized by a rapid response time and/or a high degree of accuracy.

In an exemplary embodiment of the invention, sensor 150 is operated by implementation of an algorithm summing gamma ray impacts from the radioactive source for a period of time and allowing the analytic circuitry to decide, based on the sign of total output for the entire sensor 150, in which direction and to what degree to rotate radiation detectors 522 in an effort to reach a desired rotation angle 532. Alternately, the analytic circuitry may (for example) implement an alternate algorithm which rotates radiation detectors 522 a very small amount in response to each detected impact. Alternative embodiments and performance data are presented in WO 2006/016368, the disclosure of which is fully incorporated herein by reference.

General

Systems 100 and/or sensors 150 and/or processor 170 and/or processor 180 may rely upon execution of various commands and analysis and translation of various data inputs. Any of these commands, analyses or translations may be accomplished by software, hardware or firmware according to various embodiments of the invention. In an exemplary embodiment of the invention, machine readable media contain instructions for registration of two independent position co-ordinate systems with respect to one another. In an exemplary embodiment of the invention, processor 170 and/or processor 180 executes instructions for registration of two independent position co-ordinate systems with respect to one another.

In the description and claims of the present application, each of the verbs "comprise", "include" and "have" as well as any conjugates thereof, are used to indicate that the object or objects of the verb are not necessarily a complete listing of members, components, elements or parts of the subject or subjects of the verb.

The present invention has been described using detailed descriptions of embodiments thereof that are provided by way of example and are not intended to necessarily limit the scope of the invention. In particular, numerical values may be higher or lower than ranges of numbers set forth above and still be within the scope of the invention. The described embodiments comprise different features, not all of which are required in all embodiments of the invention. Some embodiments of the

invention utilize only some of the features or possible combinations of the features. Alternatively or additionally, portions of the invention described/depicted as a single unit may reside in two or more separate physical entities which act in concert to perform the described/depicted function. Alternatively or additionally, portions of the invention described/depicted as two or more separate physical entities may be integrated into a single physical entity to perform the described/depicted function. Variations of embodiments of the present invention that are described and embodiments of the present invention comprising different combinations of features noted in the described embodiments can be combined in all possible combinations including, but not limited to use of features described in the context of one embodiment in the context of any other embodiment. The scope of the invention is limited only by the following claims.

All publications and/or patents and/or product descriptions cited in this document are fully incorporated herein by reference to the same extent as if each had been individually incorporated herein by reference.

## CLAIMS

1. A method of providing a visual indication to at least one of a position of an object inside a subject's body or a variable that may be determined according to said position, the method comprising:

   (a) detecting radiation emitted by a radiation source inside the subject's body;

   (b) analyzing the radiation to determine the position of the object; and

   (c) projecting on at least a portion of the subject's body an image providing a visual indication of the determined at least one of position or variable.

2. A method according to claim 1, wherein detecting comprises moving at least one sensor; projecting comprises operating a projector; and the position of the projector is independent of movement of the at least one sensor.

3. A method according to claim 2, wherein the projector is stationary.

4. A method according to claim 1, 2 or 3 wherein the image comprises at least one light spot surrounded with a background, and the position of the at least one light spot is indicative of the position of the object.

5. The method of claim 4, wherein the background is darker than said at least one light spot.

6. A method according to any of the preceding claims, comprising changing the position of the visual indicator in the image.

7. A method according to claim 6, wherein changing the position of the visual indicator in the image comprising digitally changing the image.

8. A method according to claim 6, wherein changing the position of the visual indicator in the image is accompanied with changing the at least portion of the body on which the image is projected.

9. A method according to claim 6, wherein changing the position of the visual indicator in the image is without changing the at least portion of the body on which the image is projected.

10. A method according to any of the preceding claims, wherein the visual indicator is indicative of at least a depth of the object inside the subject's body.

11. A method according to any of the preceding claims, wherein said object is a tissue of said body.

12. A method according to any of claims 1-10, wherein said object is a medical device.

13. A method according to claim 1, wherein the radiation is radioactive.

14. A method according to any one of the preceding claims comprising inserting the radiation source into the subject's body.

15. A system for visually indicating location of an object inside a subject's body, the system comprising:

(a) at least one radiation sensor

(b) an analyzer

(c) an image producer; and

(d) an image projector,

wherein the image producer is configured to produce an image, which upon being projected on the subject's body by said projector provides visual indication of the location of the object inside the subject's body as determined by the analyzer based on analysis of radiation sensed by the at least one radiation sensor.

16. A system according to claim 15, wherein the radiation sensor is movable independently of the image projector.

17. A system according to claim 15 or claim 16, wherein the projector is stationary.

18. A system according to any of claims 15 to 17, wherein the image producer produces the image based on data received from the analyzer, and the image is produced digitally.

19. A system according to any of claims 15 to 18, configured for digitally changing the image or replacing the image while the projector is stationary.

20. A system according to any of claims 15 to 19, wherein the radiation sensor has slatted collimators.

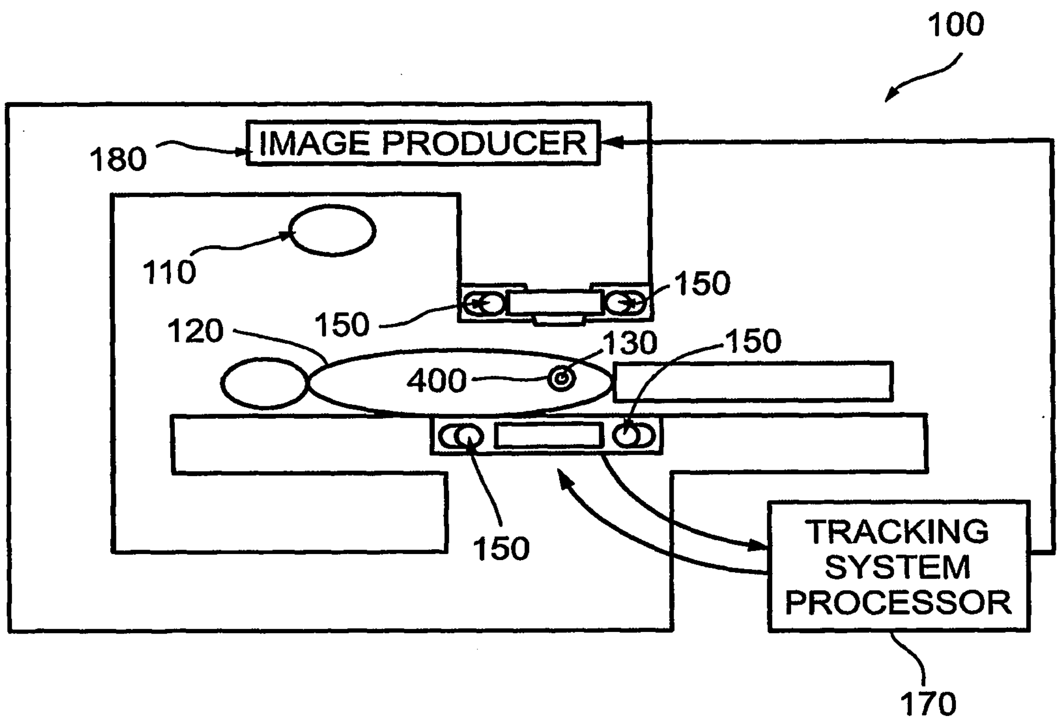
100
IMAGE PRODUCER
180
110
150
150
120
130
150
400
150
TRACKING SYSTEM PROCESSOR
170

Fig. 1a

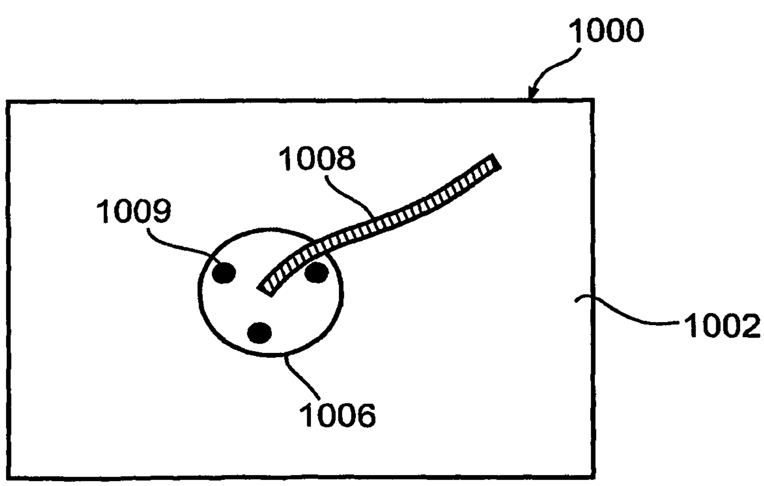
1000
1008
1009
1002
1006

Fig. 1b

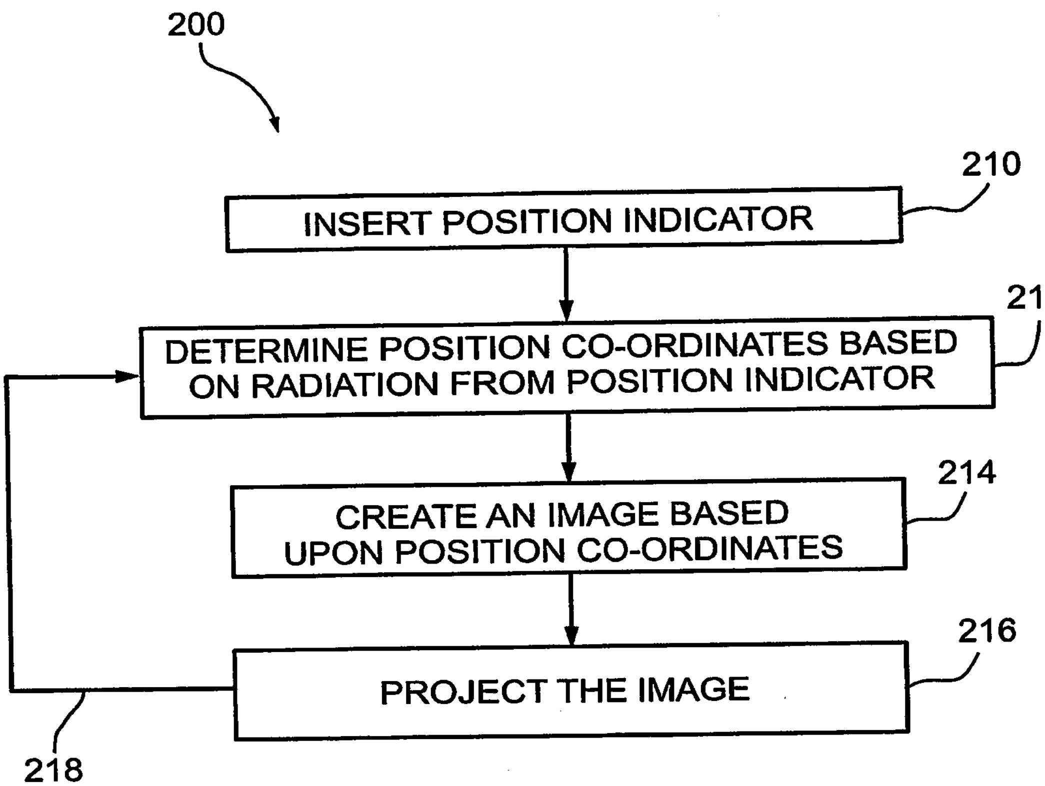
200
210
INSERT POSITION INDICATOR
212
DETERMINE POSITION CO-ORDINATES BASED ON RADIATION FROM POSITION INDICATOR
214
CREATE AN IMAGE BASED UPON POSITION CO-ORDINATES
216
PROJECT THE IMAGE
218

Fig. 2

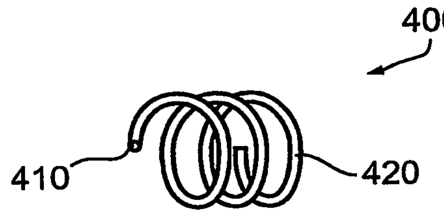


Fig. 3a

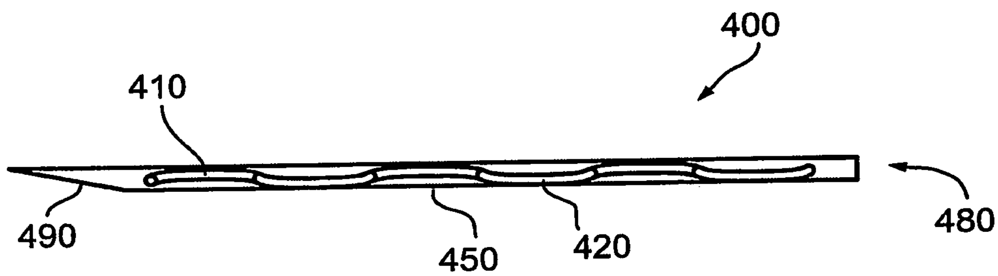


Fig. 3b

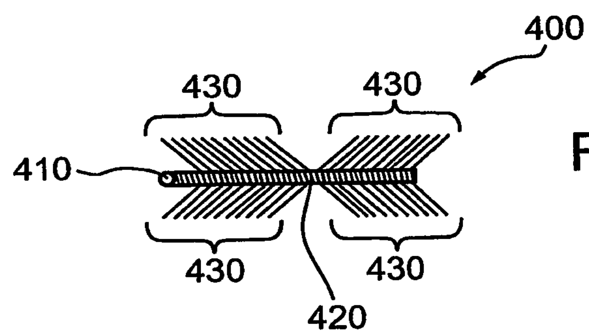


Fig. 3c

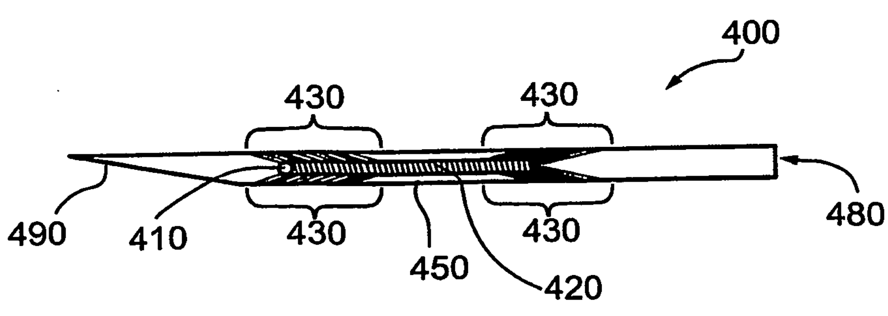


Fig. 3d

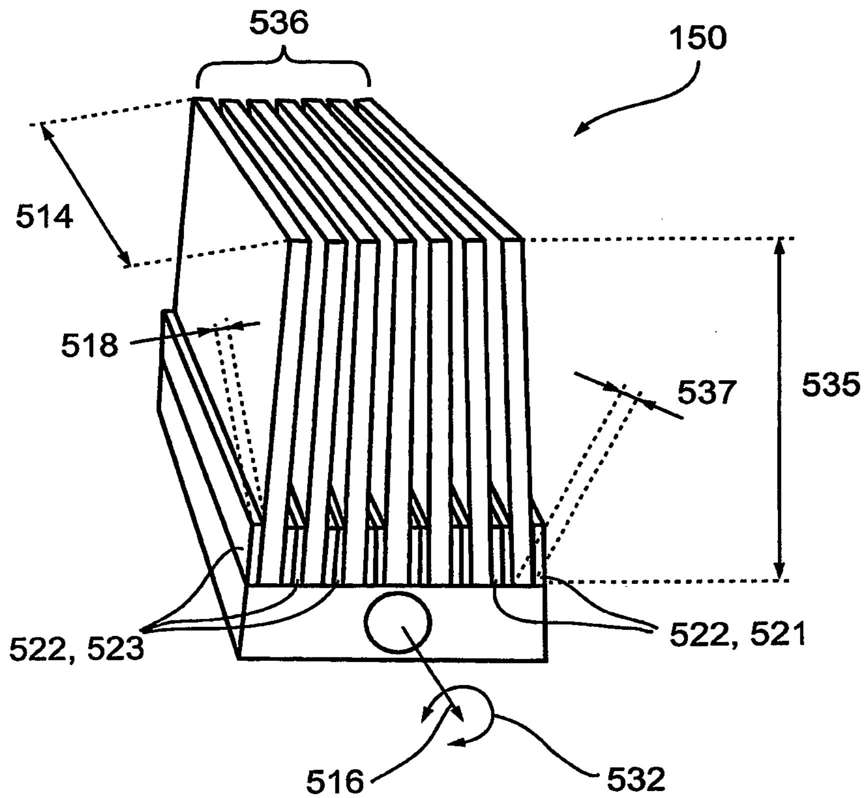


Fig. 4